IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

MEMORANDUM IN SUPPORT OF FOREST'S MOTION *IN LIMINE* 13 TO PRECLUDE PREJUDICIAL AND IRRELEVANT EVIDENCE AND ARGUMENT REGARDING FOREST'S MEDICAID REBATE SAVINGS

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A critical issue in this case is whether the amendment to the Original Lexapro Agreement (the "Lexapro Amendment") conveyed substantial value to Forest by reducing the Medicaid rebate liability that Forest owed pursuant to the Deficit Reduction Act of 2005 (the "DRA"). DPPs do not allege that Forest failed to comply with the DRA's requirements in any way or defrauded the Medicaid program. Nor do DPPs question that Forest projected that it would save tens of millions of dollars under the DRA by shifting manufacturing from Forest to Mylan via the Lexapro Amendment.

Instead of addressing the relevant issue of whether the Lexapro Agreement was an exchange of fair value, DPPs have revealed an intention to focus on irrelevant and prejudicial characterizations of Forest's Medicaid savings as exploiting a "loophole" in the law, underpaying the government, or taking money from taxpayers, such as "children, pregnant women, parents, seniors and individuals with disabilities." Such argument is irrelevant to the issues here and its probative value is substantially outweighed by the danger of unfair prejudice to Forest. Fed. R. Evid. 403. Introduction of such evidence and argument also threatens to detour the trial into a sideshow about Forest's intent with respect to the Medicaid laws, Congress's intent in passing those laws, and the possible effects of Forest's actions on Medicaid recipients. Accordingly, Forest moves to exclude all evidence and argument (1) related to Congress' intent in passing the DRA, (2) that suggests that the Lexapro Amendment enabled Forest to exploit a loophole in the law or otherwise underpay Medicaid, and (3) that suggests that Forest took money from the government, taxpayers, and Medicaid-eligible individuals.

FACTUAL BACKGROUND

On October 3, 2005, Forest entered into a distribution and supply agreement with Mylan's predecessor Alphapharm, under which Forest agreed that it would manufacture an authorized

generic version of Lexapro and supply it to Alphapharm for distribution after the brand Lexapro patent expired in 2012. *See* ECF No. 699-1, Revised Pls.' Contentions ("DPPs' Cont.") at ¶ 128. Then, in February 2006, Congress enacted the Deficit Reduction Act of 2005 (the "DRA"), which had a significant impact on the calculation of Medicaid rebates. *See* ECF No. 699-2, Defs.' Contentions ("Forest's Cont.") at 5. Under the DRA, because Forest had agreed to manufacture authorized generic Lexapro and sell it to Alphapharm, it would face substantially more Medicaid rebate liability in 2012 when it began selling the authorized generic to Alphapharm for distribution. *Id.* Thus, in 2010, Forest amended the distribution and supply agreement to transfer manufacturing responsibilities to Mylan (which acquired Alphapharm in 2007) which stood to lower Forest's Medicaid rebate liability. *Id.* at 4–5.

Forest has offered substantial evidence that the payment it made to Mylan pursuant to the Lexapro Amendment was explained, in part, by the Medicaid rebate savings Forest expected and had projected it would achieve when Mylan took over the manufacturing of authorized generic Lexapro. *See* Forest's Cont. at 4–5. For example, David Solomon, the lead negotiator of the Lexapro Amendment, testified that Forest was motivated to amend the Lexapro Agreement in large part to achieve these savings. Ex. 1, Sep. 7, 2017 Dep. of David Solomon 103:14–106:24 ("[W]e recognized that based on that existing supply arrangement we would wind up with a very significant liability due to the best price issue and so we wanted to change that – that supply arrangement, so that we were not supplying Mylan."), 110:18–111:8 (testifying that Forest projected "tens of millions of dollars" in Medicaid rebate savings).

In further support of its defense, Forest engaged as an expert witness Alexandra Mooney Bonelli, a member of Ernst & Young's Government Contract Services group and a co-leader of E&Y's Government Contract Services Pharmaceutical Pricing Team. Ms. Bonelli explains the

change in law under the DRA that occurred after the Original Lexapro Agreement was signed, and describes the DRA's impact on the calculation of Medicaid best price, which is "a main component of the Medicaid rebate." Ex. 2, Expert Rep. of Alexandra Mooney Bonelli, CFE at ¶¶ 6–29. Ms. Bonelli further opines that "it would have been reasonable for a brand pharmaceutical company in Forest's position to amend the [Original Lexapro Agreement]" to shift manufacturing responsibility to Mylan "in an effort to reduce its Medicaid rebate liability" in response to the 2006 change in law under the DRA. *Id.* at ¶¶ 6, 36–39.

DPPs do not have a Medicaid best price expert, and concede that the Medicaid law changed after the Original Lexapro Agreement in 2005 and that, due to the DRA, an agreement (like the Lexapro Amendment) under which another party took over manufacture of the Lexapro authorized generic would be valuable to Forest. ECF No. 614, Pls.' Resp. and Objections to Defs.' Statement of Undisputed Facts In Support of Defs.' Mot. for Summ. J. ("DPPs' RSOF") at ¶¶ 197–206, 214. Instead, DPPs have sought to delegitimize Forest's savings by suggesting that Forest's actions thwarted Congressional intent in passing the DRA, taking money from Medicaid-eligible patients in the process. Specifically, DPPs have suggested that Forest's Medicaid savings were an attempt to "*evade* their rebate obligations" and "charge the government more." DPPs' RSOF at ¶ 207 (emphasis added); DPPs' Cont. at ¶¶ 143 ("the Lexapro Amendment enabled Forest to *escape* $26.5 million in pre-existing Medicaid rebates") (emphasis added), 144 ("Forest's ability to *charge the government more* for branded Lexapro had no relation to the inducement or incentive for Mylan to drop the Namenda patent fight . . . Therefore the ability of Forest to *charge the government more* for branded Lexapro did not constitute 'fair value for services'") (emphasis added), 146 ("[E]ven if Forest received $26.5 million in *higher prices to the government* for branded Lexapro,

that would still represent a loss of $6 million in value compared to the $32.5 million payment.") (emphasis added).

DPPs additionally argue that "brand companies' failure to pay rebates on their authorized generics" is exploiting a "loophole" in the law that Congress intended to close through the DRA. DPPs' RSOF at ¶¶ 202–203, 204 ("the express intention of Congress in passing, and CMS in implementing, the DRA, was to close the 'loophole' by requiring brand companies to pay rebates on their authorized generic drugs."), 205, 207 ("Plaintiffs deny any suggestion that the document entitled "DRA Policy Inquiries" endorses any view that licensors of authorized generics can *evade* their rebate obligations by having the licensee manufacture and sell the authorized generic") (emphasis added), 210–211, 214. DPPs further contend that brand companies' failure to pay rebates on their authorized generic products "resulted in a loss to the government of billions of dollars." *Id.* at ¶ 205.

Moreover, during Ms. Bonelli's deposition, DPPs repeatedly sought to elicit testimony that through the Lexapro Amendment, Forest took money from the government, taxpayers, lower income individuals, children, pregnant women, parents, seniors, and individuals with disabilities. Ex. 3, Dep. of Alexandra Mooney Bonelli ("Bonelli Dep.") 108:22–24, ("Q. And under the original agreement, that $30 million would have gone to the taxpayers; isn't that right?"), 109:4–7 ("Q. Okay. But the $30 million would have gone back to the state Medicaid agencies, is that correct, under the original agreement?"), 109:13–19 ("Q. And that money, I think in your own words, would be to help finance health coverage for tens of millions of lower income Americans, including children, pregnant women, parents, seniors and individuals with disabilities; is that correct?"), 110:1–4 ("Q. Okay. But the rebate overall goes to help – goes to reimburse state Medicaid programs for the things that state Medicaid programs do; is that correct?"); 110:10–15

("Q. In your opinion is it reasonable for Forest to enter into a Lexapro amendment to keep that money for itself instead of paying it back to CMS, as was the requirement under the original agreement?").

ARGUMENT

I. DPPs Should Be Precluded from Presenting Irrelevant and Unduly Prejudicial Evidence and Argument Regarding Forest's Medicaid Rebate Savings

DPPs should be precluded from presenting argument or evidence (1) related to Congress' intent in passing the DRA, (2) that suggests that the Lexapro Amendment enabled Forest to underpay Medicaid or exploit a loophole in the law, and (3) that suggests that Forest took money from the government, taxpayers, and Medicaid-eligible individuals. This evidence has no probative value and is highly prejudicial to Forest. *See* Fed. R. Evid. 401, 402, 403.

Forest's projected Medicaid rebate savings are being offered to show that Forest's payment to Mylan under the Lexapro Amendment was "explained" as part of a fair value business deal. Forest's Cont. at 4–5; *FTC v. Actavis, Inc.*, 570 U.S. 136, 156–57 (2013) (finding that antitrust concerns are present only where a payment is large and unexplained and does not "reflect[] traditional settlement considerations, such as avoided litigation costs or fair value for services."). There is no claim—and certainly no evidence—that Forest illegally procured these savings through the Lexapro Amendment, paid less in Medicaid rebates than it owed under the law, or otherwise violated the DRA.

Yet DPPs apparently intend to elicit an emotional, policy-driven reaction from the jury by suggesting that the lawful Medicaid rebate savings are contrary to the intent of Congress and against the best interests of taxpayers and potentially the jurors themselves. However, Congress' intent in enacting the DRA is not relevant to whether Forest's payment was a large and unexplained payment under *Actavis*. *See Actavis*, 570 U.S. at 157–58 (reasoning that "[a]n unexplained large

reverse payment" triggers antitrust scrutiny). Similarly, any suggestion that Forest could or should have foregone lawful savings so that the government had more resources to treat Medicaid-eligible individuals, such as "children, pregnant women, parents, seniors and individuals with disabilities," is inflammatory and not relevant to any issue in this case.

Such evidence and argument has no effect other than to improperly "inflame the jury's passion and encourage it to render a verdict out of distaste" for Forest. *See United States Bank Nat'l Ass'n v. PHL Variable Life Ins. Co.*, 112 F. Supp. 3d 122, 139 (S.D.N.Y. 2015) (McMahon, J.) (finding that inflammatory rhetoric "which perforce results in prejudice that does not derive from proof relevant to the issues in the case" is the "very sort of prejudice against which Rule 403 guards"). Indeed, the evidence that DPPs intend to introduce and the testimony they seek to elicit mischaracterizes the Lexapro Amendment as an attempt to take money from the jurors themselves, and is "unrelated to any legitimate [argument] [DPPs] could raise in this lawsuit." *Id.* at 140; *see also* Ex. 3, Bonelli Dep. 108:22–110:15. Certainly, even if this evidence had any probative value, it is substantially outweighed by the risk of unfair prejudice to Forest, and should therefore be excluded. Fed. R. Evid. 403 advisory committee's note ("Unfair prejudice within [Rule 403's] context means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one."); *Hart v. RCI Hosp. Holdings, Inc.*, 90 F. Supp. 3d 250, 260 (S.D.N.Y. 2015) (granting motion *in limine* to exclude evidence and argument where "any such emotional reaction or policy judgment which such evidence might induce from a juror would have no proper bearing" on the issues left to be tried).

CONCLUSION

For the foregoing reasons, Forest respectfully requests that the Court grant Forest's motion *in limine* to preclude evidence and argument (1) related to Congress' intent in passing the DRA,

(2) that suggests that the Lexapro Amendment enabled Forest to exploit a loophole in the law or otherwise underpay Medicaid, and (3) that suggests that Forest took money from the government, taxpayers, and Medicaid-eligible individuals.

Dated: May 24, 2019

Respectfully submitted,

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